K131885
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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	20 June 2013
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Mounir Zaouali, RAC Regulatory Affairs Leader GE Healthcare, (GE Medical Systems, SCS) 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 45 39 Fax : + 33 1 30 70 41 40 Mounir.Zaouali@ge.com
Secondary Contact Person:	Steven Kachelmeyer, RAC Regulatory Affairs Director - X-ray GE Healthcare Phone: 262-548-2432 Fax: 262-997-1080 Steven.Kachelmeyer@med.ge.com
Device Trade Name:	eContrast
Common/Usual Name:	Full Field Digital Mammography System
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate Device(s):	Senographe Essential-P990066/S21 with Premium View i K110798

SEP 26 2013

Device Description:	The subject of this submission is a software-only option to Senographe Essential Full Field Digital Mammography (FFDM) system called eContrast. eContrast is an image post-processing algorithm that will introduce a modification to the previously approved Premium View (PV) / Premium View i (PVi) (K110798). eContrast processing will offer 6 levels of contrast strength for image viewing, where the desired combination of image sharpness, image smoothness, level of tissue penetration, and level of contrast may be selected by the radiologist. The final image appearance varies according to the selected level. eContrast is a Software only option.
Intended Use:	The Senographe DS and Senographe Essential FFDM systems generate digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe DS and Senographe Essential FFDM systems are intended to be used in the same clinical applications as traditional film-based mammographic systems. Premium View is an image-processing algorithm, which increases the visibility of breast structures. The main advantage is to provide a single breast image, where the contrast in the fatty tissues is similar to that obtained by setting WW (window width) and WL (window level) for optimum visualization of fatty tissues, and the contrast in the fibro-glandular tissue is similar to that obtained by setting WW and WL for optimal visualization of fibro-glandular tissues. Premium View I (PVi) is an option that can simplify the presentation of mammographic images, improve workflow, and streamline the review process of images with very dark or bright areas by presenting the image with the WW and WL optimized for review with minimal need for the user to make adjustments for the various tissue areas. This could be especially useful with patients who have very thin breasts, very dense breasts, or implants that currently require multiple adjustments of WW and WL to review. **eContrast** accommodates different customer display preferences in screening and diagnosis, with 5 different levels, while keeping the PVi option for implants. eContrast post-processing is also available for stereo images.

Technology:	The eContrast processing is an image post-processing that provides an image display for all breast tissue (fatty and fibroglandular) from the chest to the nipple in a single image. After acquisition, eContrast is applied to the image to create the processed image which then replaces the raw image on the screen of the acquisition workstation. The main calculations that are applied to create the processed image are: • Collimator Detection: This applies a black mask around the useful image area, covering areas which would otherwise be white. It allows more comfortable viewing. • Pseudo-log Transformation: This transformation facilitates the manipulation of brightness and contrast during the review. After the transformation, the image dynamic range is reduced to 12 bits, without loss of clinical information. • Thickness Equalization: This equalizes the grey level range all over the breast including the tissue not under compression and close to the skin line. • Dynamic Range Management: This computation locally increases contrast and sharpness for structure of interest. This effect can be reinforced based on user preferences. • Auto-contrast: This improves image quality by optimizing brightness levels (window level) and contrast (window width) in the image.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The eContrast option complies with voluntary standards. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Testing on unit level (Module verification) ▪ Integration testing (System verification) ▪ Performance testing (Verification) ▪ Safety testing (Verification) ▪ Simulated use testing (Validation)

	Summary of Clinical Tests: The subject of this premarket submission, eContrast option, included clinical testing to quantify the clinical acceptance of images that had been retrospectively processed with this image processing algorithm. The subject of this premarket submission, eContrast image processing option, included clinical image evaluation to quantify the clinical acceptance of images that had been retrospectively processed with this image processing algorithm. The objective of the eContrast clinical evaluation was to determine if the images retrospectively processed with the new processing still provided acceptable clinical image quality. The evaluation was based on BIRADS 1 or 2 patients with two fatty breasts, two dense breasts, and 2 images that were in between. This was done to show that the image processing would be acceptable across all types of patients as suggested in the Class II Special Controls Guidance Document for FFDM systems.
Conclusion:	GE Healthcare considers the eContrast option to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 26, 2013

GE Heathcare
% Mr. Mounir Zaouali
Regulatory Affairs Leader
283 Rue de la Minière
Buc, 78530
FRANCE

Re: K131885
Trade/Device Name: eContrast
Regulation Number: 21 CFR 892.1715
Regulation Name: Digital Full Field Mammography
Regulatory Class: Class II
Product Code: MUE
Dated: August 26, 2013
Received: August 28, 2013

Dear Mr. Zaouali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

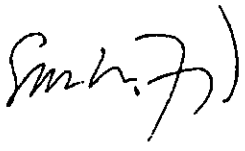
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131885

Device Name: eContrast

Indications for Use:

The Senographe Essential FFDM systems generate digital mammographic images that can be used for screening and in the diagnosis of breast cancer. The Senographe Essential FFDM systems are intended to be used in the same clinical applications as traditional film-based mammographic systems.

Premium View is an image-processing algorithm, which increases the visibility of breast structures. The main advantage is to provide a single breast image, where the contrast in the fatty tissues is similar to that obtained by setting WW (window width) and WL (window level) for optimum visualization of fatty tissues, and the contrast in the fibro-glandular tissue is similar to that obtained by setting WW and WL for optimal visualization of fibro-glandular tissues.

PVi is an option that can simplify the presentation of mammographic images, improve workflow, and streamline the review process of images with very dark or bright areas by presenting the image with the WW and WL optimized for review with minimal need for the user to make adjustments for the various tissue areas. This could be especially useful with patients who have very thin breasts, very dense breasts, or implants that currently require multiple adjustments of WW and WL to review.

eContrast accommodates different customer display preferences in screening and diagnosis, with 5 different levels, while keeping the PVi option for implants. eContrast postprocessing is also available for stereo images.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131885